

REMARKS

Amendments to the Claims

Claims 1-5 have been canceled without waiver or prejudice to filing a divisional application directed to these claims. Claim 6 has been amended by insertion of preamble language from claim 1 in order to put the claim into independent form. Applicants respectfully request entry of these amendments and submit that no new matter has been added by these amendments.

Claim Rejections

The 35 U.S.C. § 112, first paragraph rejection

Claims 1-5 have been rejected under 35 U.S.C. § 112, first paragraph as containing subject matter that was allegedly not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention. Claims 1-5 have been canceled, without waiver or prejudice, by the present amendment and therefore this rejection is moot.

The 35 U.S.C. § 103(a) rejection

The Examiner has rejected claims 1-7, 10, 14-17 and 30 under 35 U.S.C. § 103(a) for allegedly being obvious over Carpino '369 (WO97/24369) and Carpino '306 (U.S. Patent 6,107,306) in view of Hahn (Chapter 284: "Systemic Lupus Erythematosus" in Harrison's Principles of Internal Medicine, 13<sup>th</sup> Ed., 1994, 1643-1648. Specifically, the Examiner has alleged that it would have been obvious for one of ordinary skill in the art to employ the elected compound for the treatment of systemic lupus erythematosus (hereinafter SLE) over the combination of Carpino '369 and '306 and Hahn because the selected compound is useful to treat the clinical manifestation of SLE such as peripheral neuropathy and renal involvement. Applicants respectfully traverse the 35 U.S.C. § 103(a) rejection of claims 1-7, 10, 14-17 and 30. Applicants submit that present claims 1-7, 10, 14-17 and 30 are non-obvious in view of the proper combination of the Carpino and Hahn references.

Applicants agree with the Examiner's statement that the Carpino and Hahn references do not expressly teach the use of the elected compound for treating SLE. Applicants further submit that the Carpino and Hahn references also do not expressly teach or suggest the use of *any* growth hormone secretagogue for the treatment of SLE. Applicants agree with the Examiner that Carpino '369 and '306 disclose that the growth

hormone secretagogues disclosed therein are useful for improving muscle strength and mobility as well as renal homeostasis and for treating osteoporosis, improving bone remodeling, promoting cartilage formation and treating peripheral neuropathy among numerous other indications. With respect to the Hahn reference Applicants agree that the clinical manifestation of SLE can be varied. Applicants note that arthralgias, necrosis of bone, peripheral neuropathy and renal involvement are listed along with *over 50 other clinical manifestations* of SLE in Table 284-2 of the Hahn reference. Applicants also note that Table 284-2 indicates that only certain percentages of patients with SLE present with certain clinical manifestations and that a patient with SLE may not have any arthralgias, necrosis of bone, peripheral neuropathy or renal involvement. Not all patients with SLE suffer from all the symptoms and some patients with SLE may exhibit none of the symptoms in the Carpino '369 and '306 references.

In order to render the present obviousness rejection the Examiner stated that "relieving symptoms of SLE by employing the herein claimed compounds is seen to be treating SLE." Applicants reiterate that a patient with SLE may not have any of the symptoms disclosed in the Carpino references and may not have the specific symptoms that the Examiner *selected from over 50 other clinical manifestations of SLE* in Table 284-2 of the Hahn reference in rendering the present obviousness rejection. The Federal Circuit has held that "it is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art." *In re Wesslau*, 353 F.2d at 241, 147 U.S.P.Q. at 393. Applicants further submit that it is impermissible hindsight reconstruction under *In re Wesslau* reasoning for the Examiner to have selected certain symptoms of SLE as stated in Hahn for the basis of the 103 rejection when Hahn indicates that a patient with SLE may not present with any of those particular symptoms. The description of the present invention should not be used to deprecate the invention itself.

The Federal Circuit has held that "obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination." *In re Geiger*, 815 F.2d at 688, 2 U.S.P.Q.2d at 1278. Applicants submit that there is no motivation to combine the Carpino and Hahn references since there is no suggestion in these references to do so. The Carpino references in no way disclose or suggest to one of ordinary skill in the art a method of treating SLE since there is no mention of the treatment of SLE in Carpino, as acknowledged by the Examiner, and the fact that a patient with SLE may not present with any symptoms that Carpino discloses can be treated with the present growth hormone secretagogues.

Nowhere does Hahn teach or suggest growth hormone secretagogue therapy for SLE. Applicants submit that Hahn at page 1648 discloses plasmapheresis accompanied by iv cyclophosphamide, cyclosporine, iv gamma globulin, lymph node irradiation, fish oil and antibodies to T lymphocytes as experimental therapies for the treatment of SLE. Applicants note that even among the experimental therapies disclosed by Hahn there is no suggestion of the use of growth hormone secretagogues for treating SLE. According to the Hahn reference a patient suffering from SLE would not necessarily have any of the clinical manifestations recited in the Carpino references and therefore there is no reasonable likelihood of success that the growth hormone secretagogue therapy would be useful for treating SLE. In order to render the present obviousness rejection the Examiner has selected particular clinical manifestations from the 50 or more manifestations listed in the Hahn reference and from particular indications in the Carpino references. Based on the selection of clinical manifestations required from Hahn and the indications from Carpino and the fact that a patient with SLE may not exhibit any of those particular manifestations applicants submit that prior to this invention a person of ordinary skill in the art would not have been motivated to use a growth hormone secretagogue in the treatment of SLE. The Carpino and Hahn references when taken together in their entirety simply do not suggest the present invention. Applicants submit that proper combination of Carpino '369 and '306 and Hahn therefore does not render claims 6-7, 10, 14-17 and 30 obvious.

Since the use of growth hormone secretagogues for the treatment of SLE was not known or suggested prior to this invention, applicants submit that the combination therapy of growth hormone secretagogues and a second active compound such as an antimalarial or a glucocorticoid was also not known or suggested prior to this invention for the reasons stated hereinabove. The Examiner has cited *In re Kerkhoven* as holding that "combining and employing two or more agents which are known to be useful to treat SLE individually into a single composition and method useful for the same purpose is prima facie obvious." Applicants submit that the growth hormone secretagogues of formula I presently employed have never been disclosed as useful to treat SLE. Hence, Applicants submit that *In re Kerkhoven* is not applicable under the facts of this application.

Further, the Examiner has alleged at page 8 of the Office Action that management of SLE by use of NSAIDs or antibiotics somehow suggests the use of growth hormone secretagogues to relieve the symptoms of SLE. Applicants submit that the use of NSAIDs to treat pain or the use of antibiotics to treat infections does not suggest to one skilled in the art that growth hormone secretagogues are useful to treat SLE. For these reasons Applicants respectfully request the Examiner to reconsider and withdraw the 35 U.S.C. § 103(a) rejections of claims 6-7, 10, 14-17 and 30.

Reinstatement of Claims 8-9, 11-13

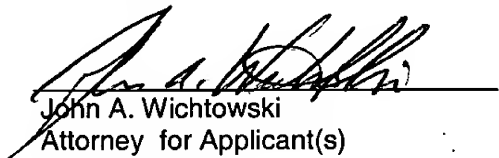
Applicants respectfully request reinstatement of claims 8-9 and 11-13 at this time. Applicants submit that claim 11 was previously improperly withdrawn since claim 11 is dependent on claim 10, which is currently being examined. Applicants submit that claims 8-9 and 12-13 are in condition for allowance and should be rejoined as they depend from linking claim 7 which applicants believe is also in condition for allowance. Claim 7 is a linking claim for claims 8-9 and 12-13 since these claims are species claims that depend from the genus recited in claim 7.

Conclusion

Applicant, having addressed all points and concerns raised by the Examiner, believes that the application is in condition for allowance and respectfully requests an early and favorable action in light of the foregoing amendment and remarks.

Respectfully submitted,

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